

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett
and Gregory S. Bartlett

v.

Civil No. 08-cv-358-JL
Opinion No. 2009 DNH 166

Mutual Pharmaceutical
Company, Inc., et al.

MEMORANDUM ORDER

Plaintiffs have filed a motion for sanctions under Rule 37 of the Federal Rules of Civil Procedure in response to the defendant Mutual Pharmaceutical Company's belated production of certain documents. After reviewing the parties' written submissions and hearing oral argument, this court grants the motion in part and denies it in part. As explained below, Mutual lacked a substantial justification for failing to produce the documents in a timely manner and is therefore subject to sanctions. Because Mutual acted in good faith, however, the court allows only some of the relief that the plaintiffs have requested.

I. Applicable legal standard

Rule 37 provides for discovery sanctions in a number of different situations, two of which the plaintiffs invoke here. The first is when a party "fails to obey an order to provide or

permit discovery." Fed. R. Civ. P. 37(b) (2) (A). As its plain language suggests, Rule 37(b) requires the moving party to establish "two things as conditions precedent to engaging the gears of the rule's sanction machinery: a court order must be in effect, and then must be violated." Ortiz-Lopez v. Sociedad Espanola de Auxilio Mutuo & Beneficencia de P.R., 248 F.3d 29, 33 (1st Cir. 2001) (quoting R.W. Int'l Corp. v. Welch Foods, Inc., 937 F.2d 11, 15 (1st Cir. 1991)).

The second situation is when a party fails to supplement its discovery responses, as required by Rule 26(e), upon learning that its earlier production is materially incomplete or incorrect. Fed. R. Civ. P. 37(c)(1). Unlike the first situation, no court order needs to be in place for the imposition of Rule 37(c) sanctions. See Ortiz-Lopez, 248 F.2d at 33; Thibeault v. Square D Co., 960 F.2d 239, 245 (1st Cir. 1992). Rather, once the moving party has shown a violation of Rule 26(e), the party facing sanctions for belated disclosure has the obligation to show that its failure to comply with the rule was either "substantially justified" or "harmless." Fed. R. Civ. P. 37(c)(1); Wilson v. Bradlees of New Eng., Inc., 250 F.3d 10, 21 (1st Cir. 2001).

II. Background

This court recently summarized the plaintiffs' allegations as follows:

In December 2004, Karen Bartlett's physician prescribed her Sulindac, a non-steroidal anti-inflammatory drug manufactured by the defendants, for pain in her right shoulder. Within weeks of filling the prescription, she went to a local emergency room complaining of "pimple like bumps, spots or blisters on her face, a fever, eye irritation," and other symptoms. She was soon diagnosed with Stevens-Johnson syndrome progressing to toxic epidermal necrolysis, a serious and potentially fatal condition characterized by large areas of lesions on and necrosis of the skin and mucous membranes. See Dorland's Illustrated Medical Dictionary 1872 (31st ed. 2007). She spent approximately three months in the hospital recovering, including two months in a medically induced coma, and emerged with permanent injuries.

Sulindac is the generic version of a drug originally approved by the FDA in 1978; the generic version at issue here was approved in 1991. The Bartletts allege that, following this approval, the defendants "had an ongoing duty to conduct postmarketing safety surveillance for any reports of serious adverse events associated with Sulindac including any such report in the medical literature" and that, had they done so, they would have uncovered information compelling them "to warn physicians about the dangers" of the drug, including associations with Stevens-Johnson syndrome and toxic epidermal necrolysis.

Bartlett v. Mut. Pharm. Co., ___ F. Supp. 2d ___, 2009 DNH 144, 3-5 (denying defendants' motion for judgment on the pleadings).

During discovery, the Bartletts requested that Mutual produce "[a]ny and all Annual and Periodic Reports filed by [defendants] for any Sulindac products." Federal regulations

require companies that hold applications for new drug approval (known as "ANDAs" and "NDAs") to file periodic reports with the Food & Drug Administration ("FDA") describing any adverse event information relating to those drugs, see 21 C.F.R. § 314.80(c)(2), and also to file annual reports that summarize any "significant new information" that might affect the drug's "safety, effectiveness, or labeling." See id. § 314.81(b)(2)(i). Reports that reflect adverse event information must be retained by the ANDA holder for at least ten years. See id. § 314.80(i). Since Mutual has held an ANDA for Sulindac since 1991, the Bartletts expected to receive at least a decade's worth of annual and periodic reports in discovery. Mutual, however, produced only three periodic reports (from 2001-02 and 2008) and no annual reports.

Shortly after this production, on January 2, 2009, the parties held a court-ordered telephone conference to address unresolved discovery issues.¹ During the conference, Mutual's

¹The relevant order stated "the court will likely assess fees and costs against the parties and/or counsel for any discovery disputes with respect to which their positions are deemed unreasonable or not well supported by applicable law." Document no. 48. About a month later, in advance of a hearing on plaintiffs' motion to compel discovery, this court again stated in a margin order that "positions deemed unreasonable by the court at the hearing will result in commensurate awards of attorneys' fees and costs."

counsel stated that "we already produced" all annual and periodic reports and that an affidavit to this effect would be forthcoming. The affidavit, signed on January 21, 2009 by Mutual's Vice President of Regulatory Affairs, Robert Dettery, stated: "Following reasonable inquiry, Mutual has produced all adverse event related documents in its possession regarding [S]ulindac, including ... periodic reports."

On August 14, 2009, one month before the scheduled close of discovery, plaintiffs' counsel mentioned to Mutual's counsel that they had been unable to locate all of the annual and periodic reports in Mutual's production. Mutual's counsel replied that "you have everything there is." But on August 28, 2009, in connection with Dettery's deposition, Mutual's counsel learned that this statement had been incorrect and that additional annual and periodic reports existed in Mutual's off-site storage, unknown to Dettery but known to his subordinate Andria Werynski, Mutual's Manager of Regulatory Affairs, who had helped with the initial production of the three periodic reports.

Mutual produced the additional periodic reports on September 1, 2009 and the additional annual reports on September 8, 2009, one week before the scheduled close of discovery and plaintiffs' expert disclosure deadline. The reports totaled 4277 pages -- more than Mutual's entire production up to that point (3687

pages). As it turned out, none of them reported any adverse events. The only three reports with adverse event information were the ones that Mutual had produced earlier in the case. Notwithstanding the late production, plaintiffs managed to review the additional reports, forward them to their experts to consider, and meet their expert disclosure deadline.

Plaintiffs now request discovery sanctions under Rule 37. Specifically, the plaintiffs have requested that the court (a) exclude the reports from evidence; (b) allow plaintiffs to conduct an on-site inspection for additional responsive documents in Mutual's possession; and (c) award attorneys' fees and costs caused by the discovery error.²

III. Analysis

Plaintiffs have invoked two separate grounds for imposing Rule 37 sanctions on Mutual: failure to comply with a discovery order under Rule 37(b) and failure to supplement discovery under Rule 37(c). As explained below, Mutual has not violated a

²In the event that such relief is denied, plaintiffs alternatively request the opportunity to conduct discovery of the facts underlying Mutual's late production. In light of the other relief granted in this order, the court need not reach -- and, in any event, declines to grant -- this alternative request. The court sees little value in conducting such discovery at this point, particularly after the extensive discussion of the underlying facts at oral argument.

specific discovery order and thus cannot be sanctioned under Rule 37(b). Nevertheless, Mutual failed to supplement its document production, which was neither substantially justified nor harmless, and is therefore subject to sanctions under Rule 37(c). Because Mutual acted in good faith, however, the court grants only some of the relief requested by plaintiffs.

A. Rule 37(b)

Plaintiffs have not established either of the two prerequisites for discovery sanctions under Rule 37(b): first, that the court issued an applicable discovery order; and second, that the defendants violated it. See Ortiz-Lopez, 248 F.3d at 33. Plaintiffs point to two general orders from this court warning the parties not to take unreasonable positions in discovery. See note 1, supra. But neither order mentions plaintiffs' request for annual and periodic reports, or even the completeness of the defendants' document production. "The proposition that an order to answer specific [discovery requests] can be implied from such a blanket directive -- a directive which does not mention the subject matter inquired into -- is inconsistent with both the structure and language of Rule 37."

R.W. Int'l Corp., 937 F.2d at 16. Accordingly, this court cannot grant discovery sanctions under Rule 37(b).³

B. Rule 37(c)

Rule 37(c) authorizes discovery sanctions when a party fails to supplement its discovery responses as required by Rule 26(e), "unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1); see also Ortiz-Lopez, 248 F.2d at 33. Rule 26(e), in turn, requires a party who has responded to a request for production to supplement or correct its response "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect." Fed. R. Civ. P. 26(e)(1). The court of appeals has said that Rule 37(c) "clearly contemplates stricter adherence to discovery requirements, and harsher sanctions for breaches." Gagnon v. Teledyne Princeton, Inc., 437 F.3d 188, 191 (1st Cir. 2006) (quotation omitted).

As an initial matter, Mutual argues that it complied with Rule 26(e) because it supplemented its production with the missing reports as soon as possible after learning that its earlier production had been incomplete -- and still met the

³At oral argument, plaintiffs' counsel appeared to concede this point.

discovery deadline. The court disagrees. Mutual has conceded that its Manager of Regulatory Affairs (Werynski) knew all along about the off-site storage of the reports, even if Mutual's counsel and its Vice President of Regulatory Affairs (Dettery) did not. Werynski helped with Mutual's earlier production of three periodic reports and easily could have been, but was not, asked to retrieve the rest of the reports. Under basic agency principles, her knowledge can be imputed to Mutual for purposes of Rule 26(e). Moreover, there is some authority for the proposition that Rule 26(e) requires a party to turn over not only responsive documents of which it is actually aware, but also documents of which it reasonably should be aware. See 7 James Wm. Moore et al., Moore's Federal Practice § 26.131[3] (3d ed. 2009) (citing Arthur v. Atkinson Freight Lines Corp., 164 F.R.D. 19, 20 (S.D.N.Y. 1995)); but see Zubulake v. UBS Warburg LLC, 229 F.R.D. 422, 433 (S.D.N.Y. 2004) (requiring "actual knowledge") (quoting F.R.C.P. 26(e), advisory committee notes (1970)). Regardless of which standard applies, Mutual both knew and should have known about the off-site reports and thus had a duty to supplement its production under Rule 26(e).

As to the timing of the additional production, Rule 26(e) requires supplementation in a "timely manner." Mutual produced the additional reports eight months after expressly representing

to the plaintiffs that all such reports had been produced. This production, while made just before the discovery deadline, was not timely. Mutual objects that the plaintiffs also waited eight months before raising concerns about the missing reports. But the duty to supplement under Rule 26(e) does not depend upon repeated requests by an adversary for updated or complete information. See AVX Corp. v. Cabot Corp., 252 F.R.D. 70, 77 (D. Mass. 2008) (citing Arthur, 164 F.R.D. at 20, and Moore, supra, at § 26.131[3]). This court therefore finds that Mutual violated Rule 26(e).

Mutual has not shown a substantial justification for its late production of the reports. Plaintiffs made a very specific request for them, which the parties expressly discussed at a court-ordered conference. Unlike a broad request for all documents relating to a given topic, which can present a complex challenge for document collection and review, this request targeted a discrete and easily identifiable set of formal FDA filings. They are standard fare for discovery in pharmaceutical litigation of this sort. Given that Mutual made a fairly small document production (less than 4000 pages) that included only three periodic reports, the absence of the remaining periodic reports and all of the annual reports (which together exceed 4000 pages) was glaring and should have caused Mutual and its counsel

to take the reasonable steps necessary to locate them. See Sheppard v. River Valley Fitness One, L.P., 428 F.3d 1, 12 (1st Cir. 2005) (stating that the phrase "substantially justified" under Rule 37 means "justified to a degree that could satisfy a reasonable person") (quoting Pierce v. Underwood, 487 U.S. 552, 565 (1988)).

Mutual claims that it failed to notice the omission because the production, which it made electronically, included a folder entitled "ANDA & FDA Correspondence." The ANDA, it says, is a living document that ordinarily would include all annual and periodic reports filed with the FDA to date. At oral argument, Mutual conceded that if someone familiar with ANDAs had reviewed the electronic folder, he or she would have known that parts of the ANDA were missing. The only person who reviewed the folder before production, however, appears to have been a paralegal checking for privilege and confidentiality (not content). This court recognizes that today's electronic productions tend to be larger and less tangible than paper productions in the past, potentially making it harder to notice omissions. But in this case, Mutual's entire production totaled less than 4000 pages, which -- regardless of format -- would not have taken long to

review.⁴ Mutual was not substantially justified in assuming that the ANDA folder contained all of the annual and periodic reports, without making a reasonable effort to verify its contents. See, e.g., Gagnon, 437 F.3d at 196 (finding no substantial justification where party did not satisfy its "obligation to investigate" the discovery issue).

Mutual also emphasizes that its senior regulatory affairs executive simply made a good-faith mistake, believing that the reports had been destroyed until he learned from a subordinate that they were actually being stored off-site. The court takes Mutual at its word. Nevertheless, even good-faith mistakes can lack a substantial justification and thus be sanctionable under Rule 37(c). See, e.g., Thibeault, 960 F.2d at 245 (mentioning "laxity" as an example). This court rejects the notion that a senior executive's belief that certain documents have been destroyed -- without personal knowledge and without consulting the employees most familiar with such documents -- relieves a company of its obligation to search any further. Here, Mutual's failure to produce the additional reports until a week before the close of discovery, despite the plaintiffs' straightforward

⁴Indeed, after catching the mistake and retrieving the additional reports, Mutual's counsel apparently took the time to review them all before production, which occurred in a matter of days. See Document no. 64, at 7 n.7.

document request and Mutual's express representation that the reports had already been produced months earlier, was not substantially justified. See Primus v. United States, 389 F.3d 231, 235 (1st Cir. 2004) (affirming Rule 37(c) sanctions where the district court "considered, but was unimpressed with, [the party's] explanations for her tardiness").

Nor can Mutual's discovery error be called harmless. The Bartletts proceeded for eight months in reliance on Mutual's false representations that all annual and periodic reports in its possession had been produced. Indeed, the Bartletts were planning to seek a spoliation instruction at trial that would allow the jury to infer that the missing reports contained adverse event information. They prepared to -- and did -- ask about the reports in multiple depositions of Mutual employees, hoping to lay the groundwork for such an instruction. Mutual's late production negated this trial strategy and the efforts devoted to it. Moreover, by the time the reports were finally produced, the Bartletts' expert disclosure deadline was only a week away. Thus, whether or not the experts ultimately referred to or relied on the new information, it had to be reviewed, analyzed, and factored into their expert disclosures on an expedited basis. These efforts may not have been devastating to the Bartletts' case, but neither were they harmless. See Primus,

389 F.3d at 236 (finding sanctions justified where "real resources were expended on legal work that was premised on" the discovery error); Gagnon, 437 F.3d at 197 (calling harmlessness "a fairly limited concept" and "the smaller escape valve in Rule 37(c)(1)"). Mutual's discovery error is therefore sanctionable under Rule 37(c).

C. ***Appropriate relief***

This court has broad discretion under Rule 37(c) to "fashion an appropriate sanction from a wide range of options." Thibeault, 960 F.2d at 245; see also LaPlace-Bayard v. Battile, 295 F.3d 157, 162 (1st Cir. 2002). These options include striking the documents from evidence, ordering payment of reasonable attorney's fees and expenses caused by the discovery error, informing the jury of the error, or imposing any "other appropriate sanctions." Fed. R. Civ. P. 37(c)(1)(A)-(C). As the court of appeals has explained, "[t]he range of sanctions provided in Rule 37(c) ... gives the district court leeway to best match the degree of non-compliance with the purpose of Rule 26's mandatory disclosure requirements." Ortiz-Lopez, 248 F.3d at 34 (citing Poulin v. Greer, 18 F.3d 979, 984 (1st Cir. 1994)). In choosing the appropriate sanction, the court may consider a variety of factors, including the reason for the error, whether

the party made it in good faith, the history of the litigation, the significance of the documents, the prejudice caused by the error, the other party's ability to overcome it, and the need to deter other litigants from disregarding procedural rules. See, e.g., Santiago-Diaz v. Laboratorio Clinico & de Referencia del Este, 456 F.3d 272, 276-77 (1st Cir. 2006); Gagnon, 437 F.3d at 199; Thibeault, 960 F.2d at 245 & n.4.

The most common sanction for Rule 37(c) violations, and the first one that the Bartletts request, is the exclusion from evidence of the relevant documents. See, e.g., Lohnes v. Level 3 Commc'ns, Inc., 272 F.3d 49, 60 (1st Cir. 2001). For more serious violations, this sanction is "near automatic." Wilson, 250 F.3d at 20. Where appropriate, however, the rule also expressly allows a court to impose other relief "instead of this sanction." Fed. R. Civ. P. 37(c) (emphasis added); see also Santiago-Diaz, 456 F.3d at 276 (confirming that "district courts have some discretion in deciding whether or not to impose that onerous sanction") (citing Jackson v. Harvard Univ., 900 F.2d 464, 468-69 (1st Cir. 1990)). In this case, the court considers exclusion to be an inappropriate remedy for a variety of reasons. First, Mutual made the discovery error in good faith, without any intent to disregard the procedural rules. Second, it is unclear which party would benefit more from the inclusion or exclusion of

the reports.⁵ Third, the plaintiffs already managed to review the documents and factor them into their expert disclosures, albeit under unnecessary time pressure, and will not be unfairly prejudiced by their inclusion in evidence going forward. In contrast, excluding the documents could leave an unexplained and potentially confusing gap in the evidentiary record at trial. See Jackson, 900 F.2d at 469 (declining to impose exclusion sanction where it would “serve[] only further to suppress evidence” and would not be “appropriate to the truth-finding process”). For all these reasons, the court declines to exclude the reports from evidence.

Next, the Bartletts request an opportunity to conduct an on-site inspection of Mutual’s computer systems, searching for emails and other documents that reflect adverse event information relating to Sulindac and four other drugs manufactured by Mutual (ibuprofen, tolmetin, indomethacin, and Bactrim). The purpose of this inspection, they say, would be to provide independent confirmation that Mutual’s production has been comprehensive.

⁵On one hand, the reports do not identify any adverse event information relating to Sulindac, making them potentially beneficial to Mutual. On the other hand, the Bartletts (despite requesting their exclusion from evidence) go so far as to call the reports “incriminatory” of Mutual in that they “demonstrate violations of the code of federal regulations.” Exclusion is less likely to be an effective remedy in these circumstances. See Fed. R. Civ. P. 37(c), advisory committee notes (1993).

Plaintiffs acknowledge that they have not targeted the four additional drugs in their prior discovery requests, but claim that recent depositions have given them reason to believe that Mutual might have learned about Sulindac's adverse effects in connection with those other drugs.

This court agrees that Mutual's late production of the annual and periodic reports, which exceeded the size of its entire original production, raises concerns about whether its production has been thorough. At the same time, the court takes Mutual at its word that it has made the production in good faith. On balance, the court finds that some "double-checking" of Mutual's production is necessary and appropriate, but that it can be conducted by Mutual and its counsel rather than by plaintiffs and their counsel, which will help to mitigate any countervailing concerns raised by Mutual about the handling of privileged materials.

As to the four additional drugs, the court considers it fair and fitting, given how long it took Mutual to produce the Sulindac reports, to allow some additional discovery at this stage by the Bartletts. They bore the burdens of Mutual's late production, and so deserve the benefits as well. Their requested discovery seems reasonably calculated to lead to the discovery of admissible evidence and, moreover, should help to confirm whether

Mutual's production as to Sulindac and its adverse effects has been comprehensive. Under the circumstances, such relief is the "best match" for Mutual's discovery error. Ortiz-Lopez, 248 F.3d at 34; cf. Jackson, 900 F.2d at 469 (deeming "further discovery" to be an appropriate "response to the problems created by [a party's] negligence").⁶

The court therefore orders Mutual to conduct a reasonable review and to confirm, in a writing submitted to this court within 45 days of this order, that it has produced to the plaintiffs all documents (including emails) in its possession, custody, or control that relate to Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms, erythema multiforme, or other serious skin reactions, in connection with any of the following five drugs: Sulindac, ibuprofen, tolmetin, indomethacin, and Bactrim (both branded and generic).

⁶The court notes that it could allow such relief even in the absence of a Rule 37(c) violation, under its inherent authority to regulate the discovery process, and, in the alternative, orders the production on that basis. See, e.g., Vineberg v. Bissonnette, 548 F.3d 50, 54-55 (1st Cir. 2008); U.S. v. Sayer, 450 F.3d 82, 89-90 (1st Cir. 2006); Williams v. Monarch Mach. Tool Co., 26 F.3d 228, 230 (1st Cir. 1994). Discovery is still underway at this point, thanks in part to Mutual's successful push, over the Bartletts' objection, for an extension of the discovery and trial schedule.

Finally, the Bartletts seek reimbursement from Mutual of their attorneys' fees and costs caused by Mutual's discovery error. The court of appeals has called this one of the "more moderate" sanctions available under Rule 37(c). Id. at 34. This court considers such an award necessary and appropriate here, given the harm that Mutual's error caused, the lack of substantial justification for the error, and the other considerations discussed above. The court therefore orders Mutual to reimburse the plaintiffs for their reasonable attorneys' fees and costs caused by the late production of the annual and periodic reports, including fees and costs associated with litigating the motion for sanctions. In light of the good-faith nature of Mutual's error, however, the court strongly cautions the plaintiffs to avoid any over-reaching as to the amount of fees and costs requested. All such fees and costs should be substantiated and clearly attributable to Mutual's late production.

IV. Conclusion

For the foregoing reasons, plaintiffs' motion for sanctions⁷ is GRANTED as to parts (b) and (c), subject to the limitations set forth in this order, and otherwise DENIED as to parts (a),

⁷Document no. 67.

(d), and (e). Mutual shall submit to this court within 45 days of this order a written confirmation that it has conducted the review and document production ordered by Part III.C, infra. In addition, if the parties cannot agree on a reasonable amount of attorneys' fees and costs, see id., plaintiffs shall submit to the court, within 14 days of this order, an itemized bill, with the opportunity for Mutual to respond within 14 days of such filing.

SO ORDERED.



Joseph N. Laplante
United States District Judge

Dated: November 2, 2009

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